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September 28, 2007

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Re App. : Stephen Nuss : Examiner Jonathan Freeman
Serial No. : 09/760,136 : Art Unit 3736
Filed : January 12, 2001 : Confirmation No. 2264
For : TITANIUM MOLYBDENUM ALLOY GUIDEWIRE

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

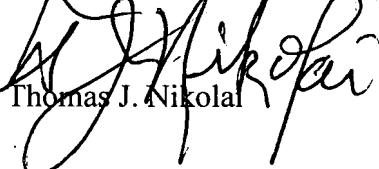
Transmitted herewith is the Appellant's Reply Brief (in triplicate) in the above-identified patent application responding to the Examiner's Answer of August 6, 2007, and replacing Appellant's Reply Brief of February 13, 2006.

The Commissioner is hereby authorized to charge any fees listed in 37 CFR 1.16 and 1.17 which may be required by this paper or credit any overpayment to Deposit Account No. 08-1265.

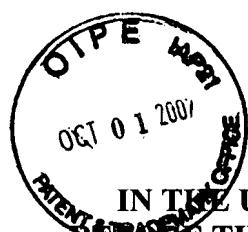
No additional fee is required.

Yours very truly,

NIKOLAI & MERSEREAU, P.A.


Thomas J. Nikolai

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Encs.



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APPELLANT'S REVISED REPLY BRIEF
37 C.F.R. §41.41

Mail Stop Appeal Brief – Patents
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P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Status of Claims

The status of claims is as set forth in Section III of Second Revised Appeal Brief for the Appellant dated November 15, 2006 and has been acknowledged as correct by the Examiner.

Grounds of Rejection for Review on Appeal

The grounds of rejection are accurately stated in the Examiner's Answer mailed August 6, 2007.

Argument

Appellant hereby responds to the revised Examiner's Answer mailed August 6, 2007.

Under Item (8) on page 3 of the Examiner's Answer, the Examiner indicates that the only evidence relied upon in the rejection of the claims under appeal are the Chapman et al. Patent 4,776,330 and the Cornish et al. Patent 6,132,389. Appellant, in Appendix B to its main Brief, included as evidence two Declarations Under 37 C.F.R. §132 by an expert in guidewire technology, Dr. Jeffrey W. Chambers. These Declarations were submitted during the *ex parte* prosecution of the application under appeal and should have been considered in making the rejection. The Board is respectfully requested to consider Dr. Chambers' averments in assessing the propriety of the rejection of Appellant's claims 13, 16-20 and 24-27 under 35 U.S.C. §103.¹

In his Declaration of July 1, 2005, after having studied the Chapman Patent 4,776,330 and the Cornish et al. Patent 6,132,389 relied upon by the Examiner for his §103 rejection, Dr. Chambers states:

"There is nothing in these patents that would lead one skilled in the art to conceive and develop an **intravascular guidewire for use in catheterization procedures**, such as in performing angiography and balloon angioplasty that is made by appropriately grinding and shaping a wire of titanium, molybdenum, zirconium and tin alloy". (Emphasis added.)

The Examiner has apparently ignored Dr. Chambers' statement to the contrary in that in his Answer, the Examiner has wrongly stated that "Chapman et al. discloses a guidewire capable of insertion into a vascular system of a patient during the course of a catheterization procedure ...". Chapman discloses a guidewire that is adapted to be inserted into a rectilinear bore drilled through the bone, the neck and the head of the

¹ Appellant has agreed that all claims stand or fall with claim 20.

femur. At most, such a guidewire would be about 10 inches in length. In accordance with the Chapman patent, the guidewire, that more appropriate should have been called a centering rod, is simply used as a centering device for a drill or reamer used to create a larger diameter bore through which an anchoring sleeve 3 and an elongated plunger 5 are to be inserted to thereby bridge a break in the neck of the femur. See col. 6, lines 26-44 of the '330 patent.

The "guidewire" 25 described in the Chapman reference is entirely unsuitable as an intravascular guidewire described and claimed by Appellant. As Dr. Chambers' states in Para. 5 of his July 1, 2005 Declaration:

"I have noted that Chapman et al. describes the use of a "guidewire" in supporting/guiding a reamer used to core out a cylindrical bore in the bone and to insert an anchor in the bore, but such guidewire would only be 10"-12" long and need not navigate any bends or curves. Hence, even if assuming *arguendo*, the guidewire in the Chapman et al. patent were made of Ti, Mb, Zr, Sn alloy, it would not in any way suggest to one skilled in the art that the alloy would lend itself to an intravascular guidewire that is typically 90"-120" in length and that must have acceptable pushability, torqueability and malleability characteristics that will allow it to be advanced through the vascular system from an area in the groin to a target cardiac blood vessel."

It is further submitted that the Examiner's contention that the guidewire 25 mentioned in the Chapman '330 patent is made from Appellant's claimed titanium, molybdenum, zirconium, tin alloy is based on speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the cited art. Nowhere within the four corners of the '330 patent is there any indication that the guidewire 25 is fabricated from appellant's claimed alloy.

While the Chapman '330 patent indicates at column 4, line 16ff, that the components of the novel kit of the invention are made of the same alloy as is used in Appellant's guidewire, nowhere in this patent is there any indication that the "kit"

includes a guidewire as one of its members. In the "Abstract" of the '330 patent, it identifies the kit components as:

- (1) An elongated epiphyseal/metaphyseal implant (1-Fig. 1);
- (2) An intramedullary rod (109-Fig. 25);
- (3) An angled side plate (43) having an elongated plate portion (45) adapted to be secured to the outer cortical wall and a hollow sleeve (47) adapted to extend into the femur (Fig. 16);
- (4) An elongated bone plate (69-Fig. 9) connectable to the angled side plate (43);
- (5) One or more additional epiphyseal/metaphyseal implants (1);
- (6) A distal buttress plate (171-Fig. 31); and
- (7) Bone screws (89, 91, 101, 103) all made from an inert, resilient, titanium-based alloy.

Nowhere is it mentioned that the kit includes a guidewire. Turning next to column 2, lines 31ff, there is again listed the components of the kit as containing (1), (2) and (3) above and a means (139) for connecting (1) above to (2) above. Then, at column 4, lines 34ff, the kit components are again listed, but without any indication that a guidewire is a member of the kit and, therefore, preferably made from Appellant's claimed titanium, molybdenum alloy.

Further, the Chapman et al. '330 patent contains no teaching or suggestion that an improved intravascular guidewire for carrying out catheterization procedures would result if a particular titanium, molybdenum, zirconium, tin alloy were used in place of the stainless steel or nickel titanium alloy (Nitinol) taught in the Cornish et al. '389 patent at column 3, line 41 thereof.

At page 6 of the Examiner's Answer, the statement is made:

"The Examiner has concluded that because the guidewire (25) forms a part of the implant, it must be part of the kit and therefore be formed of the resilient, physiologically inert titanium-based alloy."

Here, it is submitted that the Examiner has ignored the evidence of record and has resorted to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in his factual basis. As already indicated, in several places in the Chapman reference, there is a list of the kit components. Not once is a "guidewire" included as such as a component. Moreover, there is no reason why the short guidewire 25 shown in the Chapman reference cannot be fabricated from any body-compatible alloy of metal or even a medical-grade plastic, which would also be both resilient and inert. Its only function seems to be to serve as a centering member for a reaming tool used to core out a cylindrical passage through the femur to accommodate the implant used to reinforce a fracture in the femur neck (Col. 6, lines 26-44).

Appellant further submits that merely because an alloy is "resilient and inert" does not make it suitable for the fabrication of an intravascular guidewire being claimed by Appellant. "Resilient" and "inert" are relative terms. The Chapman reference says that the resilient properties of fixation rods, side plates, bone plates, etc. is advantageous in orthopedic bone repair because it minimizes "stress shielding" in which too much of the stresses applied to the femur or borne by the implant rather than the healing of bone in the fracture region (column 4, lines 23-33). This has little to do with intravascular guidewire properties that Dr. Chambers deems important, i.e., those identified in Para. 7 of the Chambers Declaration of April 20, 2004.²

² The Examiner also argues that because Chapman says that the titanium, molybdenum, zirconium, tin alloy is "resilient" and "inert", it provides a suggestion or motivation to use it in fabricating a guidewire as taught by Cornish '389. The U.S. Supreme Court has recently rejected the rule espoused by the CAFC referred to as the TSM test. See *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727.

At page 7 of the Examiner's Answer, the Examiner cites *In re Pearson*, 494 F.2d 1399, 181 U.S.P.Q. 641 (CCPA 1974) on the effect of a claim preamble as a limitation. This case is easily distinguishable on its facts. Appellant here is claiming a device, namely an intravascular guidewire, not a chemical composition as in the Pearson case. In Pearson, the Appellant admitted that the claim composition had been used prior to his invention and that the claimed use thereof did not render the composition patentable. The new use of an old composition should have been claimed as a method of treating peanut plants. In the present Appeal, there is no admission that the claimed titanium, molybdenum, zirconium, tin alloy had previously been used in fabricating an intravascular guidewire for insertion in the vascular system of a patient during the course of a catheterization procedure³, and it is submitted that Appellant's preamble does constitute a claim limitation that must be afforded weight. Specifically, a guidewire for use in catheterization procedures must possess certain well-established structural properties, e.g., pushability, torqueability, flexibility, kink resistance, formability and trackability. See Para. 7 of the Chambers Affidavit of April 20, 2004. The Chapman guidewire needs only pushability given the straight line path it needs to traverse.

The Examiner further cites *In re Ludtke*, 441 F.2d 660, 169 U.S.P.Q. 563 (CCPA 1971) for the proposition that where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the cited function. This case is inapplicable to the facts involved with the invention under appeal.

³ The evidence is to the contrary. Dr. Chambers, a knowledgeable expert in the field, has testified in Para. 9 of his Declaration of April 20, 2005, ". . . no one in the guidewire manufacturing business or in the titanium, molybdenum alloy wire business has heretofore used or proposed the use of titanium, molybdenum alloy in fabricating guidewires."

The guidewire 25 described in the Chapman reference is not capable of performing the function of an intravascular guidewire. Again, see Para. 5 of the Chambers Declaration of July 1, 2005.

In rejecting the claims on appeal under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,132,389 to Cornish et al. in view of U.S. Patent No. 4,776,330 to Chapman et al., it is asserted that the Cornish et al. reference discloses an intravascular guidewire formed of a titanium alloy, but fails to disclose the titanium alloy being claimed. The titanium alloy disclosed in the Cornish et al. patent is Nitinol and is exactly one of the alloys over which the present invention constitutes an improvement. The Examiner again erroneously asserts that Chapman discloses a guidewire capable of insertion into a vascular system during the course of a catheterization procedure. As already explained herein, the Chapman reference neither discloses a guidewire having applicant's claimed alloy composition nor an intravascular guidewire adapted for insertion into the vascular system of a patient during the course of a catheterization procedure. Instead, it is a centering insertion rod used for a completely different orthopedic procedure/application. No where in the Chapman et al. '330 reference is there any indication or even a suggestion that this centering rod is adapted for insertion into the vascular system of a patient during the course of a catheterization procedure as required by appellant's independent claims.

Given the differences between the subject matter of appellant's claims and the scope and content of the prior art as set forth above, persons of ordinary skill in the art would not have been led to create an intravascular guidewire having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight so as to achieve an

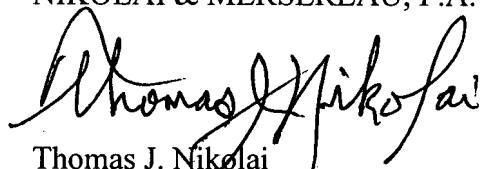
intravascular guidewire possessing the improved properties disclosed in appellant's application.

CONCLUSION

Appellant has invented an intravascular guidewire adapted to be used in catheterization procedures of a particular alloy composition that has resulted in superior physical properties when contrasted to known prior art guidewires formed of Nitinol or stainless steel. There is no teaching or suggestion in either the Chapman '330 patent or in the Cornish '389 patent that would lead one skilled in the art to use a Ti, Mb, Zr, Sn alloy in fabricating an intravascular guidewire. Hence, we submit that the Examiner has not applied the methodology set forth by the U.S. Supreme Court in *Graham v. John Deere of Kansas City*, 381 U.S. 1, in establishing a *prima facie* case of obviousness and that his rejection of Appellant's claims 12, 16-20 and 24-27 should be reversed.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Appellant's Revised Reply Brief (in triplicate), in application Serial No. 09/760,136, filed on January 12, 2001, of Stephen Nuss entitled "Titanium Molybdenum Alloy Guidewire" along with a Transmittal Letter are deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop APPEAL BRIEF - PATENTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on September 28, 2007.

Date of Signature: September 28, 2007.



Linda J. Rice
On Behalf of Thomas J. Nikolai
Attorney for Appellant